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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,225	09/29/2003	Kameron W. Maxwell	MITOS.002A	9871

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KNOBBE MARTENS OLSON & BEAR LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT PAPER NUMBER

1618

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/675,225

Applicant(s)

MAXWELL ET AL.

Examiner

James W. Rogers, Ph.D.

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 19-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The Amendment After Non-Final Rejection filed 08/15/2006 has been entered. Any rejections from the previous office action not addressed within this action have been withdrawn.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-10,12-18,20-25 are rejected under 35 U.S.C. 102(b) as being unpatentable by Mitchell et al. (US 5,462,946) for the reasons set forth in the office action mailed 04/11/2006.

Applicant's arguments filed 08/15/2006 have been fully considered but they are not persuasive.

Applicant asserts that Mitchell does not contain any disclosure related to the problem of burning caused by the use of topical formulations that left a residue on the patients skin. Applicant also asserts that Mitchell does not disclose a low residue gel or low-residue thickened liquid.

The relevance of this assertion is unclear. Firstly applicants claims are directed to a pharmaceutical composition in claims 1-15, if the composition disclosed is the same then the reference would anticipate applicants claimed invention, Mitchell does disclose the same pharmaceutical composition at least for claims 1-2, 6-10,12-15. Secondly for

claims 16-25 the claims are directed towards a method of treating a patient by applying a sufficient amount of a nitroxide radioprotector to prevent harmful side effects caused by radiotherapy. Mitchell teaches that the pharmaceutical composition can be used as a radiation protectant for skin, mucositous and hair loss, thereby meeting the limitations in claims 16-18 and 20-25. Mitchell does disclose the use of the pharmaceutical composition as an ointment, cream or lotion and an aerosol drop or spray which would satisfy the limitation of a low residue gel or low residue thickened liquid.

Applicant asserts that in order to anticipate claim 24 evaporation of the solvent must take place before the radiotherapy is applied to patient and Mitchell does not disclose the timing of applying the application before the radiotherapy is applied.

The examiner interpreted claim 24 in the broadest reasonable way, the claim only states that the method of treatment comprises applying a sufficient amount of nitroxide radioprotector, evaporating solvent and applying radiotherapy to said patient. The claim only states as currently written that the solvent evaporates, it does not disclose the solvent must all be evaporated. Indeed any reasonable solvent that would be used as a carrier in a pharmaceutical composition would evaporate almost immediately especially a more volatile carrier such as methanol for instance. As far as the time required to evaporate the solvent before applying radiotherapy Mitchell does not disclose this limitation but then neither does applicant, at least in claim 24. The examiner can only search the prior art for what is included within a claim limitation, since applicants gave no time for the evaporation of the solvent the examiner did not search this limitation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (US 5,462,946) in view of Golz-Berner et al. (US 6,426,080 B1 is used as an English equivalent to WO 99/66881) for the reasons set forth in the office action mailed 04/11/2006.

Applicant's arguments filed 08/15/2006 have been fully considered but they are not persuasive.

Applicant asserts that Golz-Berner is concerned with preparing cosmetic preparations, which are designed to keep its radical protection potential over a long period of time, which is in contrast to topical formulations that are designed to leave little

residue on the skin after a short time period. Applicant asserts this is because a significant amount of glycerine is included in many of the examples disclosed within and the presence of glycerin would not result in a low residue gel or low residue thickened liquid.

The relevance of these assertions is unclear. Firstly in regards to Golz-Berner being in contrast to applicants claimed invention because it keeps its radical protection potential over a long period of time. Golz-Berner was used primarily in combination with Mitchell for its disclosure of cosmetic active substances to protect the skin and the use of solvents, carriers and hydrogels, which are the same as applicants claimed ingredients (ethanol, propylene glycol, water and natural polymers), which Mitchell did not disclose. By combining the two references one skilled in the art could use the active disclosed in Mitchell (TEMPOL) with the solvents, carriers and hydrogels in Golz-Berner which are the same as applicants claimed invention and therefore would deliver TEMPOL in a low-residue gel or low-residue thickened liquid. Secondly the fact that Golz-Berner discloses compositions that comprise glycerine in the examples does not mean that Golz-Berner teaches away from applicants claimed invention since examples are always treated as non-limiting when applying prior art and there were several other carriers listed that would be volatile such as ethanol and water.

### ***Conclusion***

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER